Background Decisions about medical products for people with type 1 diabetes (T1D) currently focus primarily on HbA1c to assess glycemic control and as a surrogate for the risk of developing complications. Advances in T1D technology have made it feasible to assess the efficacy of therapies and technologies using a set of outcomes beyond HbA1c that better reflect day-to-day glycemic control and how a patient feels, functions and survives. However, the outcomes beyond HbA1c have not been standardized or defined consistently.

To address this issue, the T1D-stakeholder community launched the Type 1 Diabetes Outcomes Program to develop consensus definitions for a set of priority outcomes for T1D, namely hypoglycemia, time in range, hyperglycemia, diabetic ketoacidosis (DKA), and patient reported outcomes (PROs). A Steering Committee – comprised of representatives from the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the American Diabetes Association, the Endocrine Society, JDRF International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange – was the decision-making body for the T1D Outcomes Program. The work of the Steering Committee was informed by input from diabetes researchers, industry, and people with diabetes through Advisory Committees representing each stakeholder group.

Consensus Reached The Steering Committee, informed by published evidence, their clinical expertise and input from researchers, industry, and people with diabetes, developed definitions for hypoglycemia, hyperglycemia, time in range, and diabetic ketoacidosis in T1D. The definitions developed, presented in the table below, reflect the Steering Committee's assessment of the outcome's short- and long-term clinical impact on people with type 1 diabetes. The consensus was formally endorsed by the leading diabetes clinician organizations, including the American Diabetes Association (ADA) and published in Diabetes Care[1]. A press release announced the release of the publication. For PROs, the Steering Committee determined that further work is needed to develop standard PROs for T1D.

[1] Diabetes Care 2017 Dec; 40(12): 1622-1630. http://care.diabetesjournals.org/content/40/12/1622

Outcome	Definition
Hypoglycemia	• Level 1: Glucose < 70 mg/dL (3.9 mmol/L) and Glucose ≥ 54 mg/dL (3.0 mmol/L) • Level 2: Glucose < 54 mg/dL (3.0 mmol/L) • Level 3: A severe event characterized by altered mental and/or physical status requiring assistance
Hyperglycemia	• Level 1 – Elevated Glucose: Glucose > 180 mg/dL (10 mmol/L) and Glucose ≤ 250 mg/dL (13.9 mmol/L) • Level 2 – Very Elevated Glucose: Glucose > 250 mg/dL (13.9 mmol/L)
Time in Range	• Percentage of readings in the range of 70 mg/dL – 180 mg/dL (3.9-10.0 mmol/L) per unit of time
Diabetic Ketoacidosis	• Elevated serum or urine ketones (greater than the upper limit of the normal range), and • Serum bicarbonate < 15 mmol/L or Blood pH < 7.3

What is Needed? Now that consensus has been reached on definitions for the outcomes beyond HbA1c, it is important for these outcomes to be consistently utilized in clinical trials so that they become standard in the T1D community. To that end, JDRF requires that all newly JDRF-funded clinical studies incorporate the outcomes above that are appropriate for that study. Further, for those outcomes incorporated into a study, they should be consistent with the definitions from the publication (also included in the table above) and we recommend their usage as endpoints in all T1D studies. For any deviations from these definitions, a justification should be provided for our consideration.